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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,378	11/09/2001	Jeffrey T. Bluc	20455P	8714

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EXAMINER

LE, EMILY M

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/030,378	Applicant(s) BLUE, JEFFREY T.	
	Examiner Emily Le	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04/01/04, 5/06/04 and 10/07/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 18-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status Update

1. It is noted by the Office that claims 18-19, which are newly presented in the amendment filed 05/06/2004 was not fully addressed in the previous office action, mailed 07/07/2004. To correct this inadvertent omission, the Office hereby **VACATES** [emphasis added] the previous office action, mailed 07/07/2004.
2. Applicant's Notice of Appeal is noted.
3. Applicant's amendment, filed 10/07/2004 has been entered. It is noted that the amendment as filed cancels claims 9-17. Any remarks or arguments set forth in the amendment by Applicant is considered moot in view of the action set forth in paragraph no. 1 in the instant office action.
4. Claims 1-8 and 18-19 are pending and currently under examination.

Election/Restrictions

5. The following is a response to Applicant's continued traversal to the restriction requirement. Applicant's second traversal was filed in an amended dated 05/06/2004.

Applicant's traversal arguments have been fully considered. Applicant argues that the inventions have unity with one another because of a common technical feature that is present in both inventions, measuring caspase-3 activity as an indication of virus activity. Applicant also argues that the fact that Group II also contains additional steps to Group I claims does not take away from the noted technical feature being present in both sets of claims. Applicant's arguments has been fully considered, however, it is not found persuasive because the inventions lack unity with one another. The invention of

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Group I is directed at a method of assaying potency and stability of a virus, whereas, the method of Group II is directed to a method of identifying a stabilizing formulation for a virus, as originally filed. As identified in the previous office action, the special technical feature of Groups I-II is the active method steps that are recited in each group. The method step that is recited in Group II is different from that of recited in Group I. Group II requires the infections of cells with a virus that is stored in a test formulation, and measuring the caspase-3 activity induced by the virus as an indication of virus activity to determine the whether if a formulation is stabilizing. Yet, the method step of Group I requires contacting cells with a virus, and measuring caspase-3 activity as an indication of viral activity. Furthermore, the method steps recited each group is not required for the other. These two sets of inventions lack unity with one another.

The requirement is still deemed proper and is therefore made **FINAL** [emphasis added].

Sequence Compliance

6. The instant patent application is currently in compliance with the Office sequence rules.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-8 and newly added claims 18-19 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s)

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contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues that pages 5-12 of the instant specification illustrates that measuring caspase-3 activity at different times or in different formulations gives an indication of viral potency and stability. Additionally, Applicant argues that the examples provided in the specification demonstrates that the causes for apoptosis by Villa et al., cited by the Examiner in the previous office action, would not prevent the skilled artisan from practicing the claimed invention. These arguments has been fully considered, however, it is found not persuasive.

The examples, particularly pages 5-12 of the specification were fully considered. The examples on cited pages only teach that measles, mumps and rubella viruses induce caspase-3 activity. The examples do not teach a nexus between the level of caspase-3 activity measured and viral activity, wherein the specification defines viral activity as **viral stability and potency** [emphasis added], see lines 18-26 of page 1 of the specification. Furthermore, Applicant has not provided any evidence that would correlate viral stability and potency with caspase-3 activity. While is taught in the art that particular viruses induce caspase-3 activity, wherein caspase-3 mediates apoptosis, however, it is unclear how the level of caspase-3 activity measured by the claimed method can be used to render a conclusion on viral stability and potency. Applicant has not taught one skilled in the art how to account for the apoptosis that occurs as a result of different environmental conditions, other than viral infectivity.

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Without such nexus and correlation, one skilled in the art would not be able to practice the instantly claimed invention without an undue burden of experimentation. In order for one skilled in the art to practice the claimed invention, they must i) determine a nexus between caspase-3 activity and viral potency and stability, and then ii) correlate the level of caspase-3 activity observed with viral potency and stability. Such experimentation would be an undue burden upon one skilled in the art. Therefore, with Applicant's arguments fully considered, the enablement rejection stands and is also applied to newly added claims 18-19.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

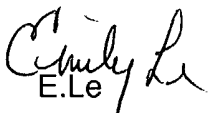
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903.

The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


E.Le


JAMES HOUSEL 11/15/04
SUPERVISORY PATENT EXAMINER
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